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Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative

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Objective. Our aim was to improve the accuracy and completeness of reporting of studies of diagnostic accuracy in order to allow readers to assess the potential for bias in a study and to evaluate the generalizability of its results.

Methods. The Standards for Reporting of Diagnostic Accuracy (STARD) steering committee searched the literature to identify publications on the appropriate conduct and reporting of diagnostic studies and extracted potential items into an extensive list. Researchers, editors and members of professional organizations shortened this list during a 2-day consensus meeting with the goal of developing a checklist and a generic flow diagram for studies of diagnostic accuracy.

Results. The search for published guidelines about diagnostic research yielded 33 previously published checklists, from which we extracted a list of 75 potential items. At the consensus meeting, participants shortened the list to a 25-item checklist, by using evidence whenever available. A prototype of a flow diagram provides information about the method of recruitment of patients, the order of test execution and the numbers of patients undergoing the test under evaluation and/or the reference standard.

Conclusions. Evaluation of research depends on complete and accurate reporting. If medical journals adopt the checklist and the flow diagram, the quality of reporting of studies of diagnostic accuracy should improve, to the advantage of clinicians, researchers, reviewers, journals and the public.

Keywords. Checklist, diagnostic accuracy, flow diagram, reporting, sensitivity and specificity.

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Introduction

The world of diagnostic tests is highly dynamic. New tests are developed at a fast rate, and the technology of existing tests is continuously being improved. Exaggerated and biased results from poorly designed and reported diagnostic studies can trigger their premature dissemination and lead physicians into making incorrect treatment decisions. A rigorous evaluation process of diagnostic tests before introduction into clinical practice could not only reduce the number of unwanted clinical consequences related to misleading estimates of test accuracy, but also limit health care costs by preventing unnecessary testing. Studies to determine the diagnostic accuracy of a test are a vital part of this evaluation process.[1–3]

In studies of diagnostic accuracy, the outcomes from one or more tests under evaluation are compared with outcomes from the reference standard, both measured in individuals who are suspected of having the condition of interest. The term *test* refers to any method for obtaining additional information on a patient's health

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status. It includes information from history and physical examination, laboratory tests, imaging tests, function tests and histopathology. The condition of interest, or *target condition*, can refer to a particular disease or to any other identifiable condition that may prompt clinical actions, such as further diagnostic testing, or the initiation, modification or termination of treatment. In this framework, the *reference standard* is considered to be the best available method for establishing the presence or absence of the condition of interest. The reference standard can be a single method, or a combination of methods, to establish the presence of the target condition. It can include laboratory tests, imaging tests and pathology, but also dedicated clinical follow-up of participants. The term *accuracy* refers to the amount of agreement between the information from the test under evaluation, referred to as the *index test*, and the reference standard. Diagnostic accuracy can be expressed in many ways, including sensitivity and specificity, likelihood ratios, diagnostic odds ratio and the area under a receiver operator characteristic (ROC) curve.[4–6]

Several potential threats to the internal and external validity of a study of diagnostic accuracy exist. A survey of studies of diagnostic accuracy published in four major medical journals between 1978 and 1993 revealed that the methodological quality was mediocre at best.[7] However, assessments were hampered because many reports lacked information on key elements of design, conduct and analysis of diagnostic studies.[7] The absence of essential information about the design and conduct of diagnostic studies has been confirmed by authors of meta-analyses.[8,9] As in any other type of research, flaws in study design can lead to biased results. One report showed that diagnostic studies with specific design features are associated with biased, optimistic estimates of diagnostic accuracy compared with studies without such deficiencies.[10]

At the 1999 Cochrane Colloquium meeting in Rome, the Cochrane Diagnostic and Screening Test Methods Working Group discussed the low methodological quality and substandard reporting of diagnostic test evaluations. The Working Group felt that the first step towards correcting these problems was to improve the quality of reporting of diagnostic studies. Following the successful CONSORT (consolidated standards of reporting trials) initiative,[11–13] the Working Group aimed to develop a checklist of items that should be included in the report of a study of diagnostic accuracy.

The objective of the Standards for Reporting of Diagnostic Accuracy (STARD) initiative is to improve the quality of reporting of studies of diagnostic accuracy. Complete and accurate reporting allows the reader to detect the potential for bias in the study (internal validity) and to assess the generalizability and applicability of the results (external validity).

Methods

The STARD steering committee (see Appendix for membership) started with an extensive search to identify publications on the conduct and reporting of diagnostic studies. This search included MEDLINE, EMBASE, BIOSIS and the methodological database from the Cochrane Collaboration up to July 2000. In addition, the members of the steering committee examined reference lists of retrieved articles, searched personal files and contacted other experts in the field of diagnostic research. They reviewed all relevant publications and extracted an extended list of potential checklist items.

Subsequently, the STARD steering committee convened a 2-day consensus meeting for invited experts from the following interest groups: researchers, editors, methodologists and professional organizations. The aim of the conference was to reduce the extended list of potential items, where appropriate, and to discuss the optimum format and phrasing of the checklist. The selection of items to retain was based on evidence whenever possible.

The meeting format consisted of a mixture of small group sessions and plenary sessions. Each small group focused on a group of related items from the list. The suggestions of the small groups were then discussed in plenary sessions. Overnight, a first draft of the STARD checklist was assembled based on suggestions from the small groups and additional remarks from the plenary sessions. All meeting attendees discussed this version the next day and made additional changes. The members of the STARD group could suggest further changes through a later round of comments by E-mail.

Potential users field-tested the conference version of the checklist and flow diagram, and additional comments were collected. This version was placed on the CONSORT website with a call for comments. The STARD steering committee discussed all comments and assembled the final checklist.

Results

The search for published guidelines for diagnostic research yielded 33 checklists. Based on these published guidelines and on input of steering and STARD group members, the steering committee assembled a list of 75 items. During the consensus meeting on 16–17 September 2000, participants consolidated and eliminated items to form the 25-item checklist. Conference members made major revisions to the phrasing and format of the checklist.

The STARD group received valuable comments and remarks during the various stages of evaluation after the conference, which resulted in the version of the STARD checklist that appears in Table 1.

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TABLE 1 *STARD checklist for the reporting of studies of diagnostic accuracy*

Section and topic	Item no.		On page no.
TITLE/ABSTRACT/	1	Identify the article as a study of diagnostic accuracy	
KEYWORDS		(recommend MeSH heading 'sensitivity and specificity')	
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups	
METHODS			
Participants	3	Describe the study population: the inclusion and exclusion criteria, setting and locations where the data were collected	
	4	Describe participant recruitment: was recruitment based on presenting symptoms, results from previous tests or the fact that the participants had received the index tests or the reference standard?	
	5	Describe participant sampling: was the study population a consecutive series of participants defined by the selection criteria in items 3 and 4? If not, specify how participants were further selected	
	6	Describe data collection: was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	
Test methods	7	Describe the reference standard and its rationale	
	8	Describe technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard	
	9	Describe definition of and rationale for the units, cutoffs and/or categories of the results of the index tests and the reference standard	
	10	Describe the number, training and expertise of the persons executing and reading the index tests and the reference standard	
	11	Describe whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers	
Statistical methods	12	Describe methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals)	
	13	Describe methods for calculating test reproducibility, if done	
RESULTS			
Participants	14	Report when study was done, including beginning and ending dates of recruitment	
	15	Report clinical and demographic characteristics of the study population (e.g. age, sex, spectrum of presenting symptoms, co-morbidity, current treatments, recruitment centres)	
	16	Report the number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended)	
Test results	17	Report time interval from the index tests to the reference standard, and any treatment administered between	
	18	Report distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition	
	19	Report a cross-tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard	
	20	Report any adverse events from performing the index tests or the reference standard	
Estimates	21	Report estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals)	
	22	Report how indeterminate results, missing responses and outliers of the index tests were handled	
	23	Report estimates of variability of diagnostic accuracy between subgroups of participants, readers or centres, if done	
	24	Report estimates of test reproducibility, if done	
DISCUSSION	25	Discuss the clinical applicability of the study findings	

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FIGURE 1 *Prototypical flow diagram of a diagnostic accuracy study*

Figure 1 shows a flow diagram that provides information about the method of recruitment of patients (e.g. based on a consecutive series of patients with specific symptoms, or of cases and controls), the order of test execution and the number of patients undergoing the test under evaluation (index test) and the reference test. We provide one prototypical flow chart that reflects the most commonly employed design in diagnostic research. Examples that reflect other designs appear on the STARD website (www.consort-statement.org\stardstatement.htm)

Discussion

The purpose of the STARD initiative is to improve the quality of reporting of diagnostic studies. The items in the checklist and the flow chart can help authors to describe essential elements of the design and conduct of their study, the execution of tests and their results.

We arranged the items under the usual headings of a medical research article, but this is not intended to dictate the order in which they have to appear within an article.

The guiding principle in the development of the STARD checklist was to select items that would help readers to judge the potential for bias in the study and to appraise the applicability of the findings. Two other general considerations shaped the content and format of the checklist. First, the STARD group believes that one general checklist for studies of diagnostic accuracy, rather than different checklists for each speciality, is likely to be more widely disseminated and perhaps

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accepted by authors, peer reviewers and journal editors. Although the evaluation of an imaging test differs from that of a test in the laboratory, we felt that these differences were more of degree than of kind. The second consideration was the development of a checklist specifically aimed at studies of diagnostic accuracy. We did not include general issues in the reporting of research findings, such as the recommendations contained in the 'uniform requirements for manuscripts submitted to biomedical journals'.[14]

Wherever possible, the STARD group based the decision to include an item on evidence linking the item to biased estimates (internal validity) or to variations in measures of diagnostic accuracy (external validity). The evidence varied from narrative articles that explained theoretical principles and papers that presented the results from statistical modelling, to empirical evidence derived from diagnostic studies. For several items, the evidence was rather limited.

A separate background document explains the meaning and rationale of each item and briefly summarizes the type and amount of evidence.[15] This background document should enhance the use, understanding and dissemination of the STARD checklist.

The STARD group put considerable effort into the development of a flow diagram for diagnostic studies. A flow diagram has the potential to communicate vital information about the design of a study and the flow of participants in a transparent manner.[16] A comparable flow diagram has become an essential element in the CONSORT standards for reporting of randomized trials.[12,16] The flow diagram could be even more essential in diagnostic studies, in view of the variety of designs employed in diagnostic research. Flow diagrams in the reports of studies of diagnostic accuracy indicate the process of sampling and selecting participants (external validity), the flow of participants in relation to the timing and outcomes of tests, the number of participants who do not receive either the index test or the reference standard, or both (potential for verification bias[17–19]), and the number of patients at each stage of the study, which provides the correct denominator for proportions (internal consistency).

The STARD group plans to measure the impact of the statement on the quality of published reports on diagnostic accuracy using a before-and-after assessment.[13] Updates of the STARD initiative's documents will be provided when new evidence on sources of bias or variability becomes available. We welcome any comments, whether on content or form, to improve the current version.

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